

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS**

JEFFREY KNUTE CONNELL,

Plaintiff,

vs.

**SECRETARY OF HEALTH AND
HUMAN SERVICES,**

Defendant

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Civil Case No. 05-4122-JPG-PMF

REPORT AND RECOMMENDATION

FRAZIER, Magistrate Judge:

Plaintiff, Jeffrey Knute Connell, filed this action seeking review of a final decision by the Secretary of the Department of Health and Human Services excluding him from participating in federal health care programs for a period of five years. Review is authorized under 42 U.S.C. §§ 405(g) and 1320a-7(f).

On March 21, 2001, following a guilty plea in U.S. District Court, Connell was convicted on charges that he violated 18 U.S.C. § 1001 on November 14, 1996, by making a false material writing or document (Count I), and violated 21 U.S.C. § 333(a)(1) on February 28, 1998, by misbranding any food or drug. Connell committed the first crime by causing an employee to falsify a record of billings submitted to the Illinois Department of Public Aid. That record failed to disclose that National Nursing Care Services, Inc. did not comply with federal regulations regarding the storage and handling of controlled substances. He committed the second crime by being in charge of a pharmacy that held misbranded drugs for sale, due to recycling and repackaging of medicine returned to the pharmacy, without regard to lot numbers or expiration dates. Connell was fined and

sentenced to serve five months in prison. Property used to facilitate the unlawful distribution of pharmaceutical controlled substances between June, 1996, and November, 1996, was forfeited.

By letter dated April 20, 2001, the Inspector General notified Connell that, as a result of his recent conviction, the Department of Health and Human Services was required to exclude him from eligibility to participate in Medicare, Medicaid, and all federal health care programs. This letter referenced § 1128(a)(1) of the Social Security Act, which is codified at 42 U.S.C. § 1320a-7(a)(1). Connell was advised that he had 30 days to submit information for consideration before a final determination regarding the length of program exclusion was made. Connell responded in writing, offering reasons why exclusion would not be justified.

In March or April, 2003, Connell entered into a consent order with the Illinois Department of Professional Regulation agreeing to a two-year suspension of his pharmacist license.

By letter dated July 16, 2003, Connell was notified that, as a result of the suspension of his state pharmacy license, the Inspector General was considering excluding him from participation in all federal health care programs pursuant to a different section of the Social Security Act. By letter dated August 26, 2003, Connell was notified that the July 16, 2003, letter was sent in error. That letter advised Connell that exclusion was warranted based on Connell's "recent" conviction.

On September 25, 2003, Connell responded, providing reasons why exclusion was not justified.

On February 27, 2004, the Inspector General notified Connell that he was excluded from participation in Medicare, Medicaid, and all federal health care programs for the minimum period of five years, based on his conviction of a criminal offense related to the delivery of an item or service under the Medicaid program. Connell received notice of the exclusion decision on March 1, 2004.

Connell appealed. An Administrative Law Judge (ALJ) reviewed written submissions and determined that the Inspector General had a legal basis to exclude Connell and that the 5-year exclusion period was reasonable. The ALJ also determined that the timing of the exclusion was discretionary and therefore unreviewable and that the notice of the exclusion was otherwise reasonable. Members of the Departmental Appeals Board declined to review the ALJ's decision.

This Court must sustain the Secretary's findings if they are supported by substantial evidence. 42 U.S.C. § 405(g). Substantial evidence is "more than a mere scintilla" of proof. The standard is satisfied by "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971); *Butera v. Apfel*, 173 F.3d 1049, 1055 (7th Cir. 1999). However, the Court does not defer to conclusions of law, and if the Secretary makes an error of law, reversal is required unless the Court is satisfied that no reasonable trier of fact could have come to a different conclusion. *Sarchet v. Chater*, 78 F.3d 305, 309 (7th Cir. 1996).

I. Reasonable Time and Laches

Connell argues that the Inspector General did not notify him of his exclusion within a reasonable time and that he suffered prejudice due to the 35-month delay between his conviction in March, 2001, and his exclusion in February, 2004. Defendant argues that the timing of the exclusion was reasonable, pointing to the absence of statutory or regulatory deadlines. Defendant also claims that plaintiff failed to show prejudice resulting from an unjustifiable delay. Because plaintiff's reasonable time argument overlaps with his assertion that the doctrine of laches serves as an equitable bar to exclusion, these arguments are addressed as one.

The Secretary, acting through the Inspector General, must exclude certain individuals and entities from participation in federal health care programs, including Medicare and Medicaid, for

a minimum period of five years. 42 U.S.C. § 1320a-7. While the Inspector General is required to provide reasonable notice of an exclusion, the timing is otherwise left to the Inspector General's discretion. 42 U.S.C. 1320a-7(f)(1). Because no statute or regulation sets a deadline for exclusion decisions, it would be improper to impose a judicial deadline. *See Heckler v. Day*, 467 U.S. 104, 117 (1984). However, federal courts may fashion an appropriate remedy in individual cases involving unreasonable administrative delay. *Id.* at 119, n. 33; *Barnett v. Bowen*, 794 F.2d 17, 22 (2nd Cir. 1986). When the timing of a decision is challenged, the Secretary must determine whether the Inspector General acted unreasonably under the circumstances. *Seide v. Shalala*, 31 F. Supp. 2d 466, 469 (E.D. Pa. 1998)(Inspector General did not act unreasonably by waiting 26 months to give notice of exclusion).

In support of his argument, plaintiff relies on *Hall v. Bowen*, 830 F.2d 906 (8th Cir. 1987), where a challenge to a lengthy delay was evaluated by the Court of Appeals in two steps. Hall's argument that a 31-month pre-exclusion delay was unreasonable was rejected due to lack of prejudice and Hall's contribution to the delay. A 22-month post-exclusion delay was found reasonable due to prompt, diligent, and sustained agency action.

This Court cannot review the Secretary's decision using the analysis outlined in *Hall* because the Secretary did not evaluate the evidence or make administrative findings regarding the reasonableness of the 35-month delay between the date of plaintiff's criminal conviction and the effective date of the Inspector General's exclusion decision. Although plaintiff challenged the delay as unreasonable and described an adverse effect on his ability to earn wages as well as great emotional distress, the ALJ did not consider this evidence or decide whether the delay was explained or justified or reasonable under the circumstances. Because the ALJ declined to address the issue and because the Departmental Appeals Board declined review, the administrative record does not

permit meaningful judicial review. *See Butera v. Apfel*, 173 F.3d 1049, 1055 (7th Cir. 1999)(a reviewing court may not make independent factual findings).

The ALJ decided that he lacked authority to evaluate the Inspector General's exercise of discretion. When the Inspector General implements a mandatory exclusion for the minimum period, ALJs review the decision solely to determine whether the basis for the imposition of the sanction exists. 42 C.F.R. § 1001.2007(a). Reversal with remand to the Secretary for a discussion of relevant information and a new decision based on the applicable legal standard is warranted under these circumstances. On remand, the Secretary should determine the appropriate person or persons to conduct the analysis and make a new decision.

II. Due Process

Plaintiff also argues that the Secretary's decision deprived him of a protected property right without due process of law. The Due Process clause requires a government entity to use constitutionally sufficient procedures when a person is deprived of a protected liberty or property interest. In order to have a property interest in a benefit conferred by the government, plaintiff must have "a legitimate claim of entitlement to it." *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972).

The Court is not persuaded that Congress conferred a benefit on plaintiff by allowing pharmacists to participate in government health programs. The goal of such programs is to confer benefits on those who seek health care, not those who serve program beneficiaries. *See Dupuy v. Samuels*, 397 F.3d 493 (7th Cir. 2005)(foster parents have no property interest in benefits paid on behalf of children in their care). Moreover, the most persuasive decisions on this issue hold that health services providers do not have a protected property interest in continued participation in government health programs. *Erickson v. U.S. ex rel. Department of Health and Human Services*,

67 F.3d 858, 861-62 (9th Cir. 1995); *Koerpel v. Heckler*, 797 F.2d 858, 863-65 (10th Cir.1986); *Cervoni v. Sec'y of Health, Ed. and Welfare*, 581 F.2d 1010 (1st Cir.1978); *but cf. Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986).

Assuming that the government conferred a benefit on plaintiff and that the benefit qualifies as a property interest in continuous participation in federal health programs, the administrative record shows that plaintiff received prior notice and a fair opportunity to be heard before he was excluded from participating in federal health care programs. The fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner. *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). This generally means that a party must have the opportunity for a hearing before the government interferes with the protected property interest. *See Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985). The administrative procedure employed was more than adequate to satisfy the Due Process clause.

IV. Relation to Delivery

Plaintiff also argues that his criminal conduct did not relate to the delivery of an item under a state health care program. He contends that his conduct relates only to the storage or labeling of controlled substances. Defendant maintains that substantial evidence supports the ALJ's finding that plaintiff's conviction related to the delivery of items or services to Illinois Medicaid recipients.

This Court's role is not to reweigh the evidence but to determine whether substantial evidence supports the ALJ's decision. *Papendick v. Sullivan*, 969 F.2d 298, 301 (7th Cir 1992), *overruled on other grounds by Johnson v. Apfel*, 189 F.3d 561 (7th Cir.1999).

In deciding whether plaintiff's criminal conduct related to the delivery of an item or service under the Illinois Medicare program, the ALJ consulted relevant documents, including plaintiff's

affidavit, the government's indictment, plaintiff's plea agreement, a consent order suspending plaintiff's pharmacy license, and an order dismissing litigation asserting a violation of the False Claims Act. These materials show that pharmacies typically receive compensation through state and federal health care programs. Plaintiff was the owner and pharmacist in charge of Family Care Nursing Home Service, which was operated using a structure located at 111 and 113 North Park Avenue in Herrin, Illinois. A large part of this business involved supplying medicines to nursing home patients who received benefits from the Illinois Department of Public Aid. Medicine was dispensed on a seven-day supply for each resident. About 60% of the nursing home residents were Medicaid recipients. Some of the medicines that were dispensed were later returned to the pharmacy. Approximately 2% were recycled and offered for sale without labels accurately displaying the lot numbers and expiration dates. After plaintiff sold his business to National Nursing Care Services, he continued to work as the pharmacist in charge. He caused an employee to falsify a billing certification to the Illinois Department of Public Aid, failed to disclose that National Nursing Care Services, Inc. had failed to properly handle and store controlled substances, and used the pharmacy building at 111 and 113 North Park Avenue to unlawfully distribute pharmaceutical controlled substances.

Plaintiff argues that the ALJ erred in concluding that his crimes were program related. He relies, in part, on a decision in related civil litigation finding insufficient proof that he made a false claim for medicaid reimbursement.

Section 1320a-7(a) mandates exclusion of individuals who have been convicted of a criminal offense that is "related to the delivery of an item or service" under a state or federal health care program. 42 U.S.C. § 1320a-7(a).

Plaintiff suggests that the evidence only supports a finding that his criminal conduct relates to the storage, handling, and misbranding of drugs and had nothing to do with delivery of any controlled substance to a consumer participating in a state health care program or a false claim for reimbursement. The Court is not persuaded that the “related to the delivery of an item or service” language requires ALJs to view the evidence narrowly. A reasonable mind could determine that the crimes plaintiff committed while owning or managing a pharmacy that dispensed medicines to some nursing home residents were related to the delivery of an item or service under a state or federal health care program. Substantial evidence supports this aspect of the Secretary’s decision.

V. Content of Exclusion Notice

Plaintiff also challenges the content of the Inspector General’s notice of exclusion. He feels that it was insufficient for the Inspector General to merely cite the exclusion statute and plaintiff’s conviction, arguing that the notice should have provided a statement of the case setting forth a discussion of the evidence and the reason or reasons upon which the exclusion determination was based.

The statute applicable to this case contains two notice provisions. Section 1320a-7(c) requires notice to the entity excluded “as may be specified in regulations” Section 1320a-7(f) generally incorporates the notice requirement in § 405(b), which governs benefit decisions made by the Commissioner of Social Security in cases involving a determination of disability. The regulation adopted regarding exclusion notices provides that an exclusion notice must be in writing and must state: (1) the basis for the exclusion, (2) the length of the exclusion, (3) the effect of the exclusion, (4) the earliest date on which a request for reconsideration will be considered, (5) the requirements and procedures for reinstatement, and (6) the appeal rights available. 42 C.F.R. 1001.2002(c). On

the other hand, § 405(b) requires “a statement of the case, in understandable language, setting forth a discussion of the evidence, and stating the Commissioner’s determination and the reason or reasons upon which it is based.” 42 U.S.C. § 405(b)(1).

The ALJ reviewed the Inspector General’s notice in light of plaintiff’s conviction and proposed exclusion notices and found no defect. The Inspector General’s exclusion notice is found at pages 66 and 67 of the record. While the notice does not meet all the notice requirements for a disability decision, it reasonably satisfies the notice requirements for an exclusion decision. In these circumstances, the finding that the Inspector General’s notice was not defective is not erroneous.

VI. Conclusion

IT IS RECOMMENDED that the Secretary’s final decision excluding Jeffrey Knute Connell be REVERSED and REMANDED to the Secretary for further proceedings and a new decision. On remand, the Secretary shall evaluate the reasonableness of the 35-month delay between plaintiff’s criminal conviction in March, 2001, and his exclusion in February, 2004. In deciding whether the delay was reasonable, the Secretary should consider the relevant circumstances, including the complexity of the issues considered, the volume of materials reviewed, any justification for delay, and the adverse impact on plaintiff.

SUBMITTED: March 7, 2007.

s/ Philip M. Frazier
PHILIP M. FRAZIER
UNITED STATES MAGISTRATE JUDGE